

510(k) SUMMARY
CORTOSS® Bone Augmentation Material

May 28, 2009

510(k) Number (if known): K080108

1. Contact Person

Catherine Moffa
Director, Regulatory Affairs
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(t) 610-640-1775 – (f) 610-640-1714

2. Device Name and Classification

Product Name:	Cortoss Bone Augmentation Material
Classification Name:	Cement, Bone, Vertebroplasty
Common or Usual Name:	Vertebral Augmentation Material
Classification Panel:	Orthopedic
Regulation Number:	888.3027
Device Class:	Class II
Product Code:	NDN

3. Substantial Equivalence

Cortoss is substantially equivalent to the following medical devices in commercial distribution:

Predicate Device	Company	FDA Clearance Number
Spineplex Radiopaque Bone Cement	Stryker	K032945
Spine-Fix Biomimetic Bone Cement	Teknimed	K043593
Staxx Fx System	Spine Wave	K053336, K063606
Confidence High Viscosity Bone Cement	Disc-O-Tech	K060300

Cortoss has the same intended use and indications, similar technological characteristics, and similar principles of operation as its predicate devices. The minor technological differences between Cortoss and its predicate devices raise no new issues of safety or effectiveness. Performance and clinical data demonstrate that Cortoss is as safe and effective as its predicate devices. Thus, Cortoss is substantially equivalent.

4. Device Description

Cortoss is a composite material that functions as a strengthening agent for injection into vertebral bodies with compression fractures or weakened bone stock. This injectable, non-resorbable synthetic material is generically referred to as a resin-based, bis-glycidyl dimethacrylate (Bis-GMA) composite.

5. Indications for Use

CORTOSS Bone Augmentation Material is indicated for the fixation of pathological fractures of the vertebral body using vertebral augmentation. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

6. Performance Data

Performance testing was conducted to ensure that Cortoss met its design specifications and performed in a manner substantially similar to the predicate devices. In all instances, Cortoss functioned as intended.

7. Clinical Data

Human clinical studies were conducted in over 500 patients at 43 clinical sites to demonstrate the safety and effectiveness of Cortoss for the treatment of vertebral compression fractures.

In the U.S., data was collected in 40 patients in two pilot studies and in 256 patients (162 Cortoss: 94 control) in a prospective, randomized, multi-center, pivotal, single-blind pivotal study. In the E.U., data was collected in over 300 patients, including a multi-center, single arm, prospective study. These European studies were conducted in four countries (France, Italy, Sweden and the UK), with follow-up ranging from six months to over three years.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthovita, Inc.
% Ms. Catherine Moffa
Director, Regulatory Affairs
45 Great Valley Parkway
Malvern, Pennsylvania 19355

JUN - 5 2009

Re: K080108

Trade/Device Name: CORTOSS® Bone Augmentation Material
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN
Dated: March 31, 2009
Received: April 1, 2009

Dear Ms. Moffa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

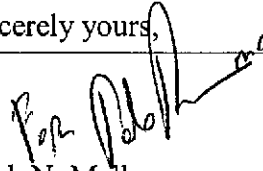
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K080108

Device Name:

CORTOSS® Bone Augmentation Material

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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